

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A composition for oral administration comprising arsenic trioxide, wherein said composition is prepared by a method comprising:

(a) adding arsenic trioxide to sterile water to form a first solution/suspension;

(b) adding sodium hydroxide to said first solution to form a second solution/suspension; and

(c) adding hydrochloric acid to said second solution to form a third solution.

2. (Original) The composition of claim 1, wherein the arsenic trioxide in step (a) is a powder.

3. (Original) The composition of claim 2, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

4. (Original) The composition of claim 1, wherein the molar concentration of the sodium hydroxide is 3M.

5. (Original) The composition of claim 1, wherein the molar concentration of the hydrochloric acid is 6M.

6. (Original) The composition of claim 5, wherein the pH of the third solution is 8.0.

7. (Original) The composition of claim 1 further comprising the step of adding dilute hydrochloric acid and sterile water to the third solution to form a final solution.

8. (Original) The composition of claim 7, wherein the final solution has a pH of 7.2.

9. (Original) The composition of claim 7, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

10. (Currently amended) A composition for oral administration comprising arsenic trioxide, wherein said composition is prepared by a method comprising:

(a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;

(b) a second step of adding 3M sodium hydroxide to said first solution/suspension to form a second solution;

(c) a third step of adding 250 ml of sterile water to said second solution to form a third solution;

(d) a fourth step of adding 6M hydrochloric acid to said third solution to form a fourth solution; and

(e) a fifth step of adding dilute hydrochloric acid and sterile water to said fourth solution to form a final solution.

11. (Original) The composition of claim 10, wherein the arsenic trioxide in step (a) is a powder.

12. (Original) The composition of claim 11, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

13. (Currently amended) The composition of claim 10, wherein the arsenic trioxide is ~~completely~~ incompletely dissolved in the first solution.

14. (Original) The composition of claim 10, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

15. (Original) The composition of claim 10, wherein the pH of the fourth solution is 8.0.

16. (Original) The composition of claim 10, wherein the final solution has a pH of 7.2.

17. (Original) The composition of claim 10, wherein the final solution has a final volume of 500 ml.

18. (Original) The composition of claim 10, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

19. (Currently amended) A method for making an arsenic trioxide composition for oral administration comprising:

(a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;

(b) a second step of adding 3M sodium hydroxide to said first solution/suspension to form a second solution;

(c) a third step of adding 250 ml of sterile water to said second solution to form a third solution;

(d) a fourth step of adding 6M hydrochloric acid to said third solution to form a fourth solution; and

(e) a fifth step of adding dilute hydrochloric acid and sterile water to said fourth solution to form a final solution. The method of claim 18, wherein the arsenic trioxide has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

20. (Original) The method of claim 19, wherein the arsenic trioxide in step (a) is a powder.

21. (Original) The method of claim 20, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

22. (Currently amended) The method of claim 19, wherein the arsenic trioxide is ~~completely~~ incompletely dissolved in the first solution.

23. (Original) The method of claim 19, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

24. (Original) The method of claim 19, wherein the pH of the fourth solution is 8.0.

25. (Original) The method of claim 19, wherein the final solution has a pH of 7.2.

26. (Original) The method of claim 19, wherein the final solution has a final volume of 500 ml.

27. (Original) The method of claim 19, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

28. (Currently amended) A method of treating hematological malignancies in a subject in need thereof, said method comprising administering to said subject a therapeutically effective amount of an arsenic trioxide composition, wherein said arsenic trioxide composition is prepared by a method comprising:

- (a) a first step of adding 500 mg of arsenic trioxide to 150 ml of sterile water to form a first solution/suspension;
- (b) a second step of adding 3M sodium hydroxide to said first solution/suspension to form a second solution;
- (c) a third step of adding 250 ml of sterile water to said second solution to form a third solution;
- (d) a fourth step of adding 6M hydrochloric acid to said third solution to form a fourth solution; and
- (e) a fifth step of adding dilute hydrochloric acid and sterile water to said fourth solution to form a final solution.

29. (Original) The method of claim 28, wherein the arsenic trioxide in step (a) is a powder.

30. (Original) The method of claim 29, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

31. (Currently amended) The method of claim 28, wherein the arsenic trioxide is ~~completely~~ incompletely dissolved in the first solution.

32. (Original) The method of claim 28, wherein the arsenic trioxide is completely dissolved prior to adding the hydrochloric acid in step (d).

33. (Original) The method of claim 28, wherein the pH of the fourth solution is 8.0.

34. (Original) The method of claim 28, wherein the final solution has a pH of 7.2.

35. (Original) The method of claim 28, wherein the final solution has a final volume of 500 ml.

36. (Original) The method of claim 28, wherein the final solution has an arsenic trioxide concentration of 1 mg/ml.

37. (Original) The method of claim 28, wherein the arsenic trioxide composition is orally administered to the subject.

38. (Original) The method of claim 37, wherein the arsenic trioxide composition is orally administered to the subject for at least a month.

39. (Currently amended) The method of claim 28, wherein the therapeutically effective amount is 10 mg per day.

40. (Original) The method of claim 28, wherein the hematological malignancies is selected from the group consisting of acute myeloid leukemia, acute nonlymphocytic leukemia, myeloblastic leukemia, promyelocytic leukemia,

myelomonocytic leukemia, monocytic leukemia, erythroleukemia, myelodysplastic syndrome, acute promyelocytic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, hairy cell leukemia, polycythemia vera, Hodgkin's lymphoma, non-Hodgkin's lymphomas, myeloma, giant cell myeloma, indolent myeloma, localized myeloma, multiple myeloma, plasma cell myeloma, sclerosing myeloma, solitary myeloma, smoldering multiple myeloma, nonsecretory myeloma, osteosclerotic myeloma, plasma cell leukemia, solitary plasmacytoma, and extramedullary plasmacytoma.

41. (Original) The method of claim 28, wherein the hematological malignancies is acute myeloid leukemia.

42. (Original) The method of claim 28, wherein the hematological malignancies is acute promyelocytic leukemia.